opioid dose of ≥50 mg oral morphine equivalents/day for ≥2 weeks and <3 rescue-free bowel movements (RFBMs)/week. Rescue laxative use was standardized and allowed if needed. Patients completed EQ-5D questionnaire on day 14 and day 28. EQ-5D index scores were compared between treatment and placebo groups using analysis of covariance, with treatment group as factor and baseline scores as covariate. **RESULTS:** Majority of the patients in the study were female (60%), Caucasian (90%), average age of 49 years and back pain (60%) was the most frequently reported pain condition. The mean daily baseline morphine equivalent opioid dose was 222 mgs. The mean ± SD baseline EQ-5D index scores were 0.45 ± 0.33 in QD, 0.47 ± 0.33 in QOD and 0.44 ± 0.35 in placebo groups respectively. The adjusted mean (± SE) change from baseline in index score on day 14 in QD (0.04 ± 0.02) and QOD groups (0.06 ± 0.02) were not statistically significant compared to placebo (0.02 ± 0.02). At the end of the double blind period (day 28), a significantly greater change from baseline in index scores was detected in the Methylnaltrexone QD dosing group (0.08 vs. –0.01; $p < 0.05$) and QOD dosing group (0.08 Vs. –0.01; $p < 0.05$) compared to placebo. **CONCLUSIONS:** Methylnaltrexone SC QD and QOD groups showed a significantly greater improvement in health related quality of life as measured by the EQ-5D index scores at the end of four weeks of therapy compared to placebo.

PGI19

PATIENT RELEVANT ASPECTS OF DIAGNOSTIC QUESTIONNAIRES AND THEIR SUBSCALES IN GASTRO-OESOPHAGEAL REFLUX DISEASE (GERD)

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OBJECTIVES: Diagnostic self-administered questionnaires for GERD are widely used and provide brief and valid measure of gastrointestinal symptoms. Beyond evaluation of symptoms and disease severity they are considered as proxy for Quality of Life (QoL) and other patients related outcome. Present study should examine relationship with patients' ability carrying out daily activities. **METHODS: Randomly selected** patients (n = 623) with chronic GERD symptoms treated by German office-based physicians in routine clinical care completed self-administered instruments for productivity (WPAI-GERD), and symptoms (RDQ, GIS, GSRS) in assessing the response to treatment. WPAI-GERD includes a visual analogue scale (0–10) to rate the impairment of the ability to do regular daily activities in the preceding week. Reported reduction of daily activities was split between patients with and without, and compared using logistic regression, accounting for the potential confounders age and PPI-medication. **RESULTS: Only one subscale from each three examined instrument—"diarrhoea"** (GSRS), "impact" (GIS) and "dyspepsia" (RDQ)—were associated with reduced productivity in daily activities in the logistic model (OR: 1.29, 3.36 and 1.46). Mean scores were 1.58 vs. 2.17 for subscale "diarrhoea", 1.38 vs. 1.91 for subscale "impact" and 0.61 vs. 1.61 for subscale "dyspepsia". Prescribed PPI-medication turned out to be independent, the odds of reduced productivity decreased with age slightly but significantly (OR 0.98). Both GSRS and RDQ have validated summary scores. "GSRS total" and "RDQ GERD" interacted strong with the dependent variable in the model (OR: 2.08 resp. 1.34). **CONCLUSIONS: Validated diagnostic questionnaires for** GERD are connected with patients' ability carrying out daily activities. However subscales insufficiently reflect the perceived impact on daily life measured by reduction in daily activities. Generic or disease specific QoL instruments should be used in addition for a comprehensive understanding of patients' burden in clinical practice.

PGI20

EFFECT OF SUBCUTANEOUS (SC) METHYLNALTREXONE ON PATIENT REPORTED CONSTIPATION SPECIFIC QUALITY OF LIFE IN A RANDOMIZED DOUBLE—BLIND CLINICAL TRIAL

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OBJECTIVES: To assess the effect of subcutaneous Methylnaltrexone on patient reported constipation specific quality of life. **METHODS:** In a double blind study 469 subjects on opioid therapy for chronic non-malignant pain and opioid-induced constipation were randomized to either methylnaltrexone QD or QOD dosing or placebo for 4 weeks and 460 received at least 1 dose. Subjects were eligible if they had an opioid dose of ≥50 mg oral morphine equivalents/day for ≥2 weeks and <3 rescue free bowel movements (RFBMs)/week. Patients reported constipation specific quality of life using the Patient Assessment of Constipation—Quality of Life (PAC-QOL) questionnaire which is a validated 28—item questionnaire assessing physical discomfort (4 items), psychosocial discomfort (8 items), worries and concerns (11 items) and treatment satisfaction (5 items) on a 5-point Likert scale. Higher scores indicate poorer QOL. Change from baseline in mean domain and total scores were compared between methylnaltrexone and placebo arms on day 28 using analysis of covariance, with treatment group as factor and baseline score as covariate. **RESULTS:** Majority of the patients in the study were female (60%), Caucasian (90%), average age was 49 years and reported back pain (60%). At the end of the double blind period (day 28), a significantly greater improvement was detected in the methylnaltrexone QD dosing group compared to placebo for: physical discomfort (–0.81 vs. –0.39;$p < 0.001$), psychosocial discomfort (–0.51 vs. –0.32; $p < 0.05$), worries and concerns (–0.69 vs. –0.38; $p < 0.001$), satisfaction (–0.96 vs.–0.48; $p < 0.001$) and overall PAC-QOL score (–0.74 vs. –0.39; $p < 0.001$). Significantly greater improvement in physical discomfort (–0.60 vs. –0.39; $p < 0.05$), satisfaction (–0.79 vs. –0.48; $p < 0.05$) and the overall PAC-QOL scores (–0.59 vs. –0.39; $p < 0.05$) were found in the methylnaltrexone QOD dosing group compared to placebo. **CONCLUSIONS:** Subcutaneous methylnaltrexone showed a significantly greater improvement in patient reported constipation specific quality of life compared to placebo.

GASTROINTESTINAL DISORDERS – Health Care Use & Policy Studies

PGI21

TREATMENT OF CHRONIC HEPATITIS C WHICH DO NOT FOLLOW CLINICAL GUIDELINES IS INCREASING DIRECT MEDICAL COSTS

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OBJECTIVES: This analysis evaluates economic impact of compliance with guidelines for treatment of Chronic Hepatitis C (CHC), where treatment decision is based on results of quantitative HCV RNA test (qRNA). **METHODS: Retrospective insurance** company database analysis of 879 patients with CHC was performed. There were 334 patients tested for qRNA during the period from 1.1.2005 till 31.8.2008. Decision tree model was developed to evaluate treatment costs when qRNA test is used for treatment termination. **RESULTS: In 2004 national guidelines for CHC were published,** which recommended examination of qRNA before and 12 weeks after treatment initiation to detect early virological response (EVR) and treatment termination in case of negative results of EVR. In 334 patients there were 611 qRNA tests performed in total (150 patients had only 1 qRNA, 113 had 2 qRNA, in 55 there were 3 consecutive qRNA performed, 16 patients had more then 4 consecutive qRNA tests). In our model, omission of EVR evaluation was defined as no or only one quantitative HCV RNA test or gap between two qRNA tests longer then 48 weeks. Omission of EVR evaluation was detected in 166 patients. In a decision tree model taking into account EVR results (followed by appropriate treatment termination) it was calculated that treatment cost in this group of 166 patients could be €4,013,880, while the treatment of the same group with omission of EVR evaluation would be €4,870,440. **CONCLUSIONS: In** analyzed group of 334 patients with HCV, there were almost 50% of cases were treatment termination could not be evaluated in accordance with valid guidelines, because of inappropriate performance of quantitative HCV RNA tests. Calculated savings are €856,560 in this group of patients. Preparation and implementation of clinical practice guidelines in national health and drug policy could have cost saving effect.

PGI22

CIRCULAR STAPLED HAEMORRHOIDOPEXY IN THE TREATMENT OF HAEMORRHOIDAL PROLAPSE: HTA REPORT—LOMBARDIA REGION, ITALY

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OBJECTIVES: Surgical management of Haemorrhoidal Disease includes Milligan-Morgan (MM) haemorrhoidectomy and stapled haemorrhoidopexy (PPH, Procedure for Prolapse and Haemorrhoids), which excises prolapsing tissues, whilst maintaining physiological functioning of haemorrhoidal plexus. Scope of work was to develop an HTA Report evaluating PPH in terms of clinical, ethical, social, organizational and economic impact. **METHODS: Literature search on Medline/PubMed, Embase data-**bases; analysis of the clinical course for PPH vs. MM at 3 Hospitals in Lombardia Region: bottom-up costing of the surgical course (surgery, hospital admission) and of the global course (clinical evaluation, surgical course, follow-up phase). Medical resources, collected by structured questionnaires, were valued (Euro 2008) on the basis of full hospital costs (personnel, operating theatre, hospital stay), regional outpatient tariffs (diagnostics), market prices (drugs, medical devices) and average per-capita Gross Domestic Product (working days). **RESULTS: Cost analysis of the surgical** course showed Hospital direct costs per patient/case of €2306 and €1558 respectively for PPH and MM (difference €748); and for the global course €2532 for PPH and €1781 for MM; these values exceed the fixed regional DRG 158 tariff (€1209) for hospital reimbursement. Sensitivity analyses, based on published meta-analysis data, confirmed the robustness of basecase results. Average regained productivity was estimated to be 11.3 working days/year, with a potential social benefit of €752/patient. The budget impact analysis, based on the difference of cost (€748) between the surgical courses to be applied as an extra-tariff for PPH, and on regional statistics for the intervention, estimated an extra-cost ranging from +1.7% to +16% over the current regional funding for the procedure of €9.24 **mio/year. CONCLUSIONS: Analysis of** hospital disease management courses for haemorrhoidal disease showed the inadequacy of current funding for both surgical procedures, and provided an estimation of the effect of suggested tariff increase in order to adequately fund the local providers of Lombardia.